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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,953	02/12/2004	Scott Cordray	3091-0	5981

7590                    05/01/2009  
JOHN LEZDEY AND ASSOCIATES  
SUITE 118  
2401 WEST BAY DRIVE  
LARGO, FL 33770

EXAMINER
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CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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05/01/2009            PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/018,953	CORDRAY, SCOTT
	<b>Examiner</b>	<b>Art Unit</b>
	FRANK I. CHOI	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 April 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 36-44 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 36, 38 are objected to because of the following informalities: Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995). The Applicant can use parentheses around or in front of the sub-paragraph letters or remove the sub-paragraph letters altogether. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 937 453 A2 in view of Gennaro, Shippert (US Pat. 5,713, 855) and Picciano (US Pat. 5,897,872).

EP 0 937 453 A2 discloses a nasal spray formulation composition containing Dead Sea salts (31-35% MgCl<sub>2</sub>, 24-26% KCl, 4-8 NaCl, 0.4-0.6% CaCl<sub>2</sub>, water) for treatment of nasal or sinus congestion and to soothe coughing irritations due to bronchitis or similar conditions (Pg. 3, lines 26-39, Pg. 5, lines 43-60, Pgs. 6-7, Pg. 8, lines 1-15, 34, 24).

Gennaro discloses that pharmaceutical preparations are typically sterile, nasal solutions are typically aqueous, isotonic and slightly buffered to maintain a pH of 5.5 to 6.5 and, optionally, contain preservatives and stabilizers, and various aerosol preparations and devices, including methods of producing aerosol in situ (Pgs. 1293, 1500, 1662-1677).

Shippert discloses a device for treating bleeding in the nasal or sinus passage after surgery or due to a wound which delivers an irrigation solution, such as a saline solution (Columns 1, 2).

Picciano discloses the use of a nasal spray containing a saline solution which is used to treat sinusitis, sino-nasal congestion, rhinosinusitis and inhalant allergy (Columns 7, 8).

EP 0937453 discloses a nasal spray formulation composition containing Dead Sea salts (31-35% MgCl<sub>2</sub>, 24-26% KCl, 4-8 NaCl, 0.4-0.6% CaCl<sub>2</sub>, water) for treatment of nasal or sinus congestion and to soothe coughing irritations due to bronchitis or similar conditions. The difference between EP 0937453 and the claimed invention is that EP 0937453 does not expressly disclose a nasal spray formulation comprising said Dead Sea salts which contains a buffer or is present in the amount of 0.5 to about 5 grams per liter of solution, or a method of treating rhinitis, sinusitis, epistaxis and post surgical irrigation using said Dead Sea Salts.

However, the prior art amply suggests the same the EP 0937453 discloses a nasal spray formulation for treatment of nasal or sinus congestion; Remingtons discloses that pharmaceutical preparations are typically sterile, nasal solutions are typically aqueous, isotonic and slightly buffered to maintain a pH of 5.5 to 6.5 and, optionally, contain preservatives and stabilizers, and various aerosol preparations and devices, including methods of producing aerosol in situ; Shippert discloses the use of saline solutions for irrigation of the nasal passages, in the treatment of nasal bleeding due to surgery or other injury; and Picciano discloses the use of a nasal spray containing a saline solution which is used to treat sinusitis, sino-nasal congestion, rhinosinusitis and inhalant allergy. As such it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as

above with the expectation of formulating a nasal spray which would be effective in treating rhinitis, sinusitis, epistaxis and post-surgical irrigation.

It is noted that this PCT case claims priority to U.S. Application Serial No. 09/345,043, filed 6/30/99. However, that U.S. Application does not appear to disclose a buffer, pH, amount in grams per liter of aqueous solution or the specific claimed composition. As such, although EP 0 937 453 A2 was published after the priority date but before the international filing date, its disclosure is still prior art as to Claims 36-44.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

Art Unit: 1616

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi

Patent Examiner

Technology Center 1600

May 1, 2009

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616